

28. (Amended) A textile graft comprising:
an elongate woven tubular body of set diameter having a fabric wall of thickness not exceeding 0.16 mm; said graft being radially compressible for catheter delivery and returnable to an open tubular configuration of said set diameter upon deployment.

REMARKS

The application has been amended. Claim 17 and 28 have been amended.
Reconsideration is respectfully requested.

The Examiner has indicated that the reissue application was filed without the required offer to surrender the original patent. Pursuant to 37 C.F.R. § 1.178, Applicants have filed an Offer to Surrender the original patent. That Offer to Surrender was filed December 15, 1999 by the inventors of the application and includes consent of the assignee including the appropriate statement under 37 C.F.R. § 3.73(b). Prior to allowance of the application and the reissue of the patent, the original patent will be surrendered or an affidavit or declaration will be provided regarding the unavailability of the original patent. Reconsideration is respectfully requested.

The drawings are objected to under 37 C.F.R. § 1.83(a). The Examiner contends that "the warp yarns, weft yarns, denier of the yarns, any multifilament yarns and picks per layer per inch (as stated in claims 19-23) must be shown or the features cancelled from the claims." This determination is respectfully traversed.

Claims 19-23 claim specific parameters with regard to the weaving of the textile graft of the present invention. Figures 1 and 2 clearly show in, partial cross section, that the graft is formed of woven textile materials. Having clearly shown the textile material in the drawings, the drawing are believed to support the specific features recited in claims 19-23 as best as can be presented. The specification of the present application clearly refers to woven synthetic fibers shown in Figure 2 and further describes with specificity the limitations set forth in claims 19-23. Accordingly, reconsideration of the drawing requirement is respectfully requested.

The Examiner has indicated that claims 6-10 are allowed. This determination is gratefully acknowledged.

The Examiner has further indicated that claims 3-5, 13, 14, 23, 31, and 32 contain allowable subject matter. While this determination is also gratefully acknowledged, independent claims from which allowable claims depend are believed to be distinguishable over the cited references and, as will be described in further detail hereinbelow, define patentably over the prior art.

Independent claims 11 and 17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,282,847 to Trescony et al. (Trescony). Independent claims 1 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Trescony in view of U.S. Patent No. 5, 275,222 to Lazarus. These determinations are respectfully traversed.

Independent claim 1 and 11 are directed to a woven textile prosthetic implant including an elongate tubular body where the tubular body includes plurality of longitudinally spaced wave-like crimps along the length thereof. As set forth in the specification of the present invention, the longitudinally spaced wave-like crimps enhance the pliability and ease of handling as well as the structure stability of the tube. The longitudinally extending wave-like crimps of the present invention further provide longitudinal flexibility while maintaining sufficient tubular integrity. Furthermore, the crimps permit the graft to be easily flexed to permit ease of implantation especially where the graft must be implanted over a torturous course.

The Trescony reference discloses a vascular graft of tubular construction. The graft of Trescony includes a plurality of longitudinally extending transversely spaced pleats. The pleats of Trescony allow the diameter of the tube to expand and contract.

As set forth in Trescony, the pleats are provided so that when the graft is subjected to normal physiological blood pressures, the pleats unfold or expand so that the diameter of the graft changes. Trescony specifically relies on the unfolding of the pleats so that when the graft diameter expands, there is little or no change in the total surface area of the graft. This is described in Trescony at column 3, lines 14-28.

FIGS. 3 and 4 are sectional views of a preferred graft 10 shown as it appears when subjected normal physiological blood pressures. As shown in FIG. 3, graft 10, having an apparent diameter A, is pleated and sized to maintain its fully relaxed pleated form at the lowest normal blood pressure. At the highest pressure, the cross-sectional area is substantially increased due to unfolding of the pleats 12, providing the graft with a new larger apparent diameter B. Preferably the graft 10 remains slightly pleated at highest normal

blood pressure, as shown in FIG. 4, so that the enlargement in cross-sectional area produces little to no change in wall perimeter dimension. Thus, under normal conditions there is little or no tensile stress on the graft wall due to normal pulsing blood flow therethrough.

As can be seen, the pleats provided by Trescony are designed to allow expansion and contraction of the diameter of the tubular member forming the graft.

In contrast, the longitudinally spaced crimps of the present invention, which extend radially about the tube, provide for no change in diameter of the graft. The crimps instead provide for longitudinal flexibility of the graft making it easier to implant. The Trescony reference fails to show, in any regard, a plurality of longitudinally spaced wave-like crimps. Therefore, Trescony cannot anticipate the present invention.

Furthermore, noting the deficiencies of Trescony, Lazarus fails to fill those deficiencies. Lazarus is cited by the Examiner as teaching the use of a radiopaque marker. As it relates to claims in the present application, Lazarus fails to show a graft having a plurality of longitudinally spaced wave-like crimps along the length of a tubular graft body.

Accordingly, it is respectfully submitted that independent claims 1, 11 as well as the claims which depend therefrom are patentability distinct over Trescony as well as the combination of Trescony and Lazarus.

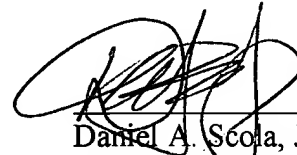
Independent claims 17 and 28 are directed to a textile graft formed of an elongate tubular body where the tubular body has a set diameter. The set diameter of the tubular body is more fully described in the present specification at column 4, lines 10-17. As noted above, the graft shown in Trescony is designed with a plurality of transversely spaced longitudinally extending pleats. The pleats are specifically employed to allow the diameter of the tube to expand as a result of normal blood pressure. The Trescony graft provides "little or no tensile stress on the graft walls due to normal pulsing blood flow therethrough." In order to eliminate said stress, Trescony provides longitudinal pleats which allow expansion of the graft diameter.

In the present invention, as set forth in independent claims 17 and 28, a textile graft is provided where textile graft includes a tubular body having a set diameter. Claims 17 and 28 further recite that the tubular configuration of the textile graft is formed by a fabric wall having a thickness not exceeding 0.16 mm. Trescony fails to show such a wall thickness where the wall itself is not subject to expansion and maintains a set diameter after implantation and during use. As Trescony fails to disclose, teach or suggest the features recited in claims 17 and 28 and as Lazarus fails to meet the deficiencies of Trescony, independent claims 17 and 28 as well as the claims which depend therefrom are believed to be patentably distinct.

Having responded in full to the present Office Action, it is respectfully submitted that the application, including claims 1-32 is in condition for allowance. Favorable action thereon is respectfully solicited.

Should the Examiner have any questions or comments regarding this submission, the Examiner is invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. Scola, Jr.', is written over a horizontal line.

Daniel A. Scola, Jr.
Registration No.: 29,855
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700